Filtration efficiency of surgical face masks: The need for more meaningful standards

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In recent years improvement of the filtration efficiency of surgical face masks has been emphasized as a result of concern over the protection of the patient and increasing concern for protection of the user of the mask. The increase in concern about acquired immunodeficiency syndrome and the use of laser surgery with its associated aerosol plume created by vaporization of tissue has required the surgical face mask industry to attempt to quantify the efficiency of the masks for removal of particles. At the same time, the medical profession is seeking and demanding more efficient masks or other protective methods to minimize exposure. Because no one standard method is universally acceptable for determination of the efficiency of face masks, concern has been expressed that the efficiencies reported by different suppliers are not always comparable because the test methods may not be the same.

Of even greater concern is the possibility that reported efficiencies may have little relevance in that the values may be based on tests that are not representative of the intended end use of the filters. Two such end uses will be presented to illustrate the current problem.

The primary purpose of any filtration test method should be to provide information that is relevant to the end use. In the case of the surgical face mask, one purpose of the face mask, probably the original purpose, is to protect the patient from being contaminated by bacteria expelled from the health care worker during normal breathing and/or coughing. A second purpose that has emerged more recently is the protection of the worker from contamination. These purposes may seem to be the same; however, as I will explain, they are fundamentally different in several aspects.

In the first case the primary objective is to prevent the direct expulsion of bacteria from the worker to the patient. Without the mask even normal breathing could transport biologic contaminants toward the patient. The mask physically filters the expelled air, thereby removing the contaminants, and disperses the air in a less direct way. Depending on how well the mask fits, some air will escape unfiltered by passing around the edges of the mask. However, the mask does block the direct path, minimizing the risk of direct impact of contaminants on the patient. In the second case the worker may depend on the mask to remove biologic contaminants that are present in the air. In this case the suspended contaminants are filtered as the worker inhales; unfiltered air may also pass around the edge of the mask.

TEST METHODS IN CURRENT USE

One test method designed to measure the efficiency of surgical face masks is the bacterial filtration efficiency (BFE) test. In the BFE test a water-based aerosol containing bacteria is used to measure the retention efficiencies of filters. Although biologic assays are noted for greater variability than are physical assays, biologic tests have been considered more appli-

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cable for determining the reliability of surgical face masks that are expected to filter out microorganisms.

Two versions of BFE tests have been used in the past: the in vitro method[1] and the in vivo[2] method. In the in vitro BFE test a surgical face mask is challenged with a mist produced by aerosolizing *Staphylococcus aureus* bacteria with 0.1% peptone water in a standard nebulizer. In the in vivo BFE tests, a face mask worn by a person is challenged with the natural aerosol of water and bacteria emitted by a person while simulating a cough several times. Thus both BFE procedures are based on solid bacteria that are suspended in and transported by water droplets.

In both BFE tests the bacteria penetrating the mask are collected, cultured, and then counted to determine the number penetrating the mask. A similar test, without the face mask in place, allows a determination of the initial number of bacteria. The inlet and outlet numbers are used to determine the filtration efficiency. These bacterial filtration tests require 24 to 48 hours to culture the colonies and therefore cannot be used to monitor and control the quality of current face mask production. In addition, the tests are subject to greater experimental error because of inherent variations in biologic testing. Nevertheless, these two types of BFE test procedures have been used by the surgical face mask industry to evaluate product reliability.

In 1983 Wadsworth and Davis[3,4] developed a simulated BFE test referred to as the filtration efficiency test (FET), which was shown to correlate well with the BFE test. In this test monodisperse polystyrene latex spheres (PSLs) were substituted for the bacteria and a particle counter was used to count the particles passing through the filter. The technique had several advantages over the BFE tests. It allowed the test time to be reduced to less than 5 minutes compared with a 2-day test for the BFE. It also allowed for thousands of particles to be used as opposed to approximately 100 bacteria, improving the accuracy and reproducibility of repeated tests. This provided rapid feedback in the production of the media and faster turnaround in the development of higher efficiency filters used in the masks.

DEFICIENCIES IN CURRENT METHODS

It should be emphasized that both of these tests (in vitro BFE and FET), as originally designed, were intended to measure the efficiency of the masks for prevention of direct impact through the mask. In reality, both methods measure the ability of the "flat" mask to remove droplets of approximately 2 to 3 μm containing suspended *S. aureus* bacteria 0.810 μm in diameter[5] (BFE test) or PSLs 0.804 μm in diameter (FET).[3] In both cases the media become wet during the test, increasing efficiency as the test progresses. In effect, the efficiency measured by the in vitro BFE test is an average value integrated during the test period, whereas the FET represents a specific point in time. This is not critical if the test results are used as relative indicators of performance. Excellent correlations were reported between the two tests.[4]

As a result of possible edge leakage in the actual face mask, however, neither test can be used to guarantee that, if the BFE or FET is 99.9%, the face mask will remove 99.9% of all particles expelled by the worker. Qualitatively, however, it does indicate that the mask will be effective in preventing the direct expulsion of and impact of contaminants onto the patient.

To imply from the BFE test or the FET that the user (or worker) is protected from 99.9% of the contaminants in the room is incorrect. A 99.9% efficient mask that has a face fit leakage of 5% around the edges is essentially a 95% effective filter. In other words, a mask is only as good as its fit in protecting the wearer. As the mask becomes wetted as a result of the exhalation of moist air, the resistance to air flow through the mask may increase, resulting in increased air leakage by the edges of the mask. This is especially true in the case of the smaller submicron particles generated during laser surgery, because these particles have no tendency to impact out as they are transported by the air that passes around the edge of the mask. The larger particles (>4 to 5 μm) have a greater tendency to be impacted out of the air stream, resulting in an overall efficiency between the 95% and 99.9% used in the example. The existing standard tests have not addressed either the edge leakage or the effect that prolonged use might have on edge leakage.

As a result of concern over laser-generated

particles, it was brought to my attention recently that some testing may have been conducted with the BFE test or the FET in which submicron particles (<0.8 μm) were being used. The objective was to identify the efficiency of the masks for 0.3 to 1.0 μm particles or contaminants. Because the droplets in these tests are much larger than the particles and because the particles are suspended in the droplets, the BFE test or FET would tend to yield efficiencies that were similar to that of the droplets, not the particles, because the particles are an integral part of the droplets. This would result in the possibility of significantly overestimating the efficiency for these smaller sizes, leading one to a false security that the mask was protecting the wearer from these submicron particles. If one could assume that biologic contaminants or particles were always suspended in droplets of the size used in the BFE or FET, then these results would probably be representative.

In the case of laser surgery it has been reported that the generated smoke was found to consist of particles having a median diameter of 0.31 μm, with a range of 0.1 to 0.8 μm.[6] This is considerably smaller than the droplets being tested in the BFE test or FET. To illustrate this Wadsworth and Davis[4] reported that tests of a 0.3 μm aerosol (dioctyl phthalate aerosol) on a surgical face mask showed an efficiency of 31% compared with 98.9% for the in vitro BFE test. Although the BFE test may simulate the ability of the surgical face mask to block the direct impact of contamination to the patient, the 0.3 μm aerosol test is more likely to provide an indication of the protection to the wearer from the laser plume, which is not suspended in larger droplets. The question as to whether the laser plume can actually contain bacteria or cancer cells is yet another issue, not addressed herein, that further complicates the issue.

The FET as developed by Wadsworth and Davis[4] was designed to simulate the BFE test. However, the concern as to whether the BFE test or the FET is a representative test depends on the end use. In the case of concerns over protection of the user or wearer, the methods have three shortcomings: (1) neither measures the edge leakage, (2) each measures the efficiency of removal of 0.8 μm bacteria or PSLs suspended in large droplets (2 to 3 μm), and (3) the BFE test and FET efficiencies may be significantly higher than the actual efficiency of the mask in its end use, resulting in a false sense of security.

In conclusion, there is a growing need to develop and adopt a standardized test method designed to evaluate the ability of surgical face masks to protect the wearer from exposure to contamination from a variety of particle sizes. This need is not necessarily met by the use of existing BFE test or FET methods. It is more likely that this method would need to incorporate (1) droplets smaller than those used in these tests (such as is currently employed in standard dioctyl phthalate aerosol droplet tests) or (2) monodisperse solid particles (PSLs) as used in the American Society for Testing Materials' recently developed test method to determine the efficiency of flat filter media at different particle sizes.[7] Both these methods measure the true penetration of the submicron particles or droplets, whereas the BFE test and the FET are influenced by the carrier droplets, resulting in high efficiencies. In addition, techniques need to be developed to quantify edge leakage. The expertise to develop such standards is available within the many professional organizations, research laboratories, and product development laboratories associated with the filtration and surgical face mask industries.

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